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The role of self-treatment guidelines in self-management education for adult asthmatics

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Guidelines on asthma management have changed considerably in the last two decades. Patient education has gained in popularity and especially asthma self-management training is thought to be essential in the treatment of adult asthma. Since 1989 many researchers have added self-treatment guidelines to self-management programmes and several studies have found improvements in health outcomes, such as lung function, quality of life, use of health care facilities and asthma symptoms. However, because of the lack of proper control groups, it is not clear whether this has to be attributed to self-treatment guidelines or to, for example, more education or more medical attention. The only two studies that were placebo controlled did not show an effect of self-treatment.

To assess the added benefit of self-treatment guidelines to a self-management programme, randomized 'placebo' controlled trials of sufficient size with sufficient follow-up time are necessary. The only difference between intervention and control groups should be guidelines for self-treatment.

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Introduction

Guidelines on asthma management have changed considerably in the last two decades. Patient education has gained in popularity and especially asthma self-management training is thought to be essential in the treatment of adult asthma (1,2). However, only a few publications are available as to what constitutes self-management. Two aspects in the management of a patients asthma will be discussed: self-management and self-treatment. In this paper 'self-management' will be defined as effective behaviour with regard to asthma, based on sufficient knowledge about asthma and its provoking factors, adequate coping behaviour, compliance with inhaled medication, attention to changes in the severity of the disease, adequate inhalation technique and the correct use of a peak flow meter. One of the components of self-management believed to be of importance is the self-adjustment of the inhaled medication by the patient with changing disease severity. We will use the term 'self-treatment' when patients are provided with guidelines to self-adjust their inhaled steroids or to start a short course of oral steroids when necessary, based on peak expiratory flow (PEF) values and/or symptom perception.

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The first study that formally provided self-treatment guidelines as part of a self-management programme, was performed by Beasley *et al.* in 1989 (3). Their impressive results inspired many researchers and clinicians to add self-treatment guidelines to self-management programmes (4–18). However, its efficacy remains to be proven, because most studies were designed to evaluate a self-management programme as a whole, including education, more (medical) attention and guidelines for self-treatment. Therefore they were not able to demonstrate the efficacy of self-treatment guidelines. This paper is aimed at evaluating available knowledge on the efficacy of self-treatment guidelines.

The Rationale of Self-treatment Guidelines

Intuitively, self-treatment is a very appealing concept. When patients are taught to self-intervene early in case of an asthma exacerbation, an acute deterioration in lung function could be curtailed at an early stage, which could result in reduced morbidity and mortality. Patients would probably feel more confident about their disease, and their quality of life and lung function could improve. Because the need for medical interventions would be less, costs could be reduced. This almost sounds too good to be true. On the other hand, the question arises whether the same results could be accomplished by educating patients thoroughly about their asthma, its provoking factors and their

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medication use, and by giving them more time and attention and finally by optimizing their treatment, without issuing formal written self-treatment guidelines.

What would then be the rationale for a written self-treatment plan? The theory behind self-treatment guidelines is that increasing knowledge of asthma is not sufficient to change behaviour of asthmatic patients and does not lead to improved health (19). One way to achieve behavioural changes is to increase the patients self-efficacy expectations, preferably by letting the patient experience successful behaviour (20). Self-treatment would fit very well in this approach.

The Available Evidence for Efficacy of Self-treatment

A literature search (Medline SilverPlatter) for the period 1985 through November 1996 was performed to identify self-management trials that incorporated self-treatment guidelines in their programme. The following combination of keywords was used: (asthma and adult) and (self-care or self-administration or self-medication or patient education). This rendered 273 articles, of which only papers in English, dealing with structured education in adult asthmatics, were included. All abstracts were read to assess whether self-treatment was part of the education. This resulted in 31 articles, which were thoroughly screened for the presence of self-treatment guidelines, after which 16 remained. Two papers described different aspects of the same study (7,15) so 15 independent studies were finally selected. The main characteristics for both controlled and uncontrolled studies are summarized (Tables 1 and 2).

Beasley and colleagues (U.K., 1989) (3) evaluated instructions on how to use a self-treatment plan in an uncontrolled trial. They found an increase in lung function (FEV_1 and FVC) and reductions in days lost from school or work, nocturnal wakenings and use of oral steroids and antibiotics. Interpretation is difficult, because medical treatment was optimized (more inhaled steroids) and more attention was given.

Worth (Germany, 1990) (9) performed a 1-year, before–after, uncontrolled trial in 58 patients in which an extensive 5-day inpatient educational programme was evaluated. Nocturnal attacks, exacerbations, sick-leave days and hospitalizations were approximately halved in the year following the intervention, compared with the year before.

Mayo *et al.* (U.S.A., 1990) (4) evaluated a two-step self-treatment plan among severe asthma patients requiring multiple hospitalizations, in a randomized controlled trial (RCT). When patients experienced a severe attack, they had to take oral prednisone for 3 days and they had to increase their inhaled steroids for 1 week. They found an impressive reduction in hospital admissions and hospital days.

Ringsberg and co-workers (Sweden, 1990) (6) evaluated an 'asthma school'. Although they state that early drug treatment was part of the programme, it is unclear whether formal self-treatment with written guidelines was part of it. Quality of life increased in both groups, while the number of days in hospital decreased relatively more in the intervention group (83%) than in the control group (74%). It is striking that FEV_1 values increased significantly only in the control group.

Charlton and colleagues (UK, 1990 and 1991) (7,15) randomly allocated asthma patients into a group receiving peak-flow-based self-management and a group receiving symptom-based self-management, all based on individual counselling. They observed a reduction in doctor consultations, the need for oral steroids and days lost from work or school.

Mühlhauser *et al.* (Germany, 1991) (5) evaluated the same programme as Worth (9) in a large ($n^{-1}=132$) before–after, uncontrolled trial in which an extensive 5-day inpatient educational programme was evaluated during 1 yr. The number of exacerbations, hospitalizations and days lost from work decreased.

Charlton and co-workers (U.K., 1992) (14) also evaluated a nurse-run asthma clinic with 105 patients who were given self-treatment guidelines based on both peak flow and symptoms. Improvements were recorded for attacks of wheeze, nocturnal asthma attacks, overall trouble with asthma, interference of asthma in the patients life, walking uphill, climbing stairs, general practitioner home visits and the number of days lost from work or school.

Yoon *et al.* (Australia, 1993) (8) performed an RCT with 76 patients and found a reduction in re-admission rate and emergency room visits in the intervention group compared with the control group.

The GRASSIC study (U.K., 1994) (18) evaluated a three-step self-treatment plan among asthma patients who were not already using a PEF meter. When PEF fell below a certain level (individually tailored, but without further details), patients had to take oral prednisone. If PEF fell further, below another (unspecified) level, patients should seek immediate medical assistance. This was a randomized placebo-controlled trial among 569 patients. Patients were not formally educated, although a subgroup of 137 patients in the intervention group and 143 from the control group received educational booklets. The intervention group received a PEF meter and guidelines on how to use it. Oral steroids were prescribed more often to patients with severe asthma in the intervention group, and patients with a PEF meter who also received 'integrated' care reported less restricted activity. No effect of the booklets was reported and no other differences between the two groups were found.

D'Souza and co-workers (New Zealand, 1994) (10) introduced a 'credit-card' self-management plan in a Maori community. Despite the short follow-up period (16 weeks), results were impressive: a 12% increase in peak flow was observed, the percentage of nights woken and days out of action was approximately halved, and a three-fold reduction in emergency department visits and hospital admissions was found.

Boulet and colleagues (Canada, 1995) (13) did a 'case-controlled retrospective study' in which patients were matched for age, sex and medication needs. In comparison with the control group, the intervention group showed a reduction in the number of days off work and emergency room visits.

TABLE 1. Overview of published articles on self-treatment guidelines, scored on aspects of relevance, validity, and power

	Relevance					Validity			Sufficient power and maximum efficiency			
Study	Behavioural intervention	Behaviour evaluated	Follow-up period months	Representative sample	Inhaled steroids	Randomization	Placebo controlled	Double blind	*n**	Homogeneous groups	Potential for improvement	Stable patients
Beasley *et al.* (3) (1989)	−	−	6	+	−	−	−	−	36	±	+	+
Worth (9) (1990)	−	−	12	+	−	−	−	−	58	?	?	?
Mayo *et al.* (4) (1990)	−	−	8	+	−	+	−	−	47–57	−	+	−
Ringsberg *et al.* (6) (1990)	−	−	12	+	−	+	−	−	20–18	?	+	?
Charlton *et al* (7,15) 1990 and 1991)	−	−	12	−	+	−	−	−	69	−	+	+
Mühlhauser *et al.* (5) (1991)	−	−	12	+	−	−	−	−	142	+	+	−
Charlton *et al.* (14) (1992)	−	−	12	−	+	−	−	−	105	−	+	+
Yoon *et al.* (8) (1993)	−	+	10	−	−	+	−	−	37–39	+	+	?
GRASSIC (18) (1994)	−	+	12	−	−	+	+	−	285–284	+	+	?
D'Souza *et al.* (10) (1994)	−	−	4	−	−	−	−	−	47	?	+	−
Boulet *et al.* (13) (1995)	−	+	12	+	+	±	−	−	42–42	?	?	+
Ignacio-Garcia *et al.* (11) (1995)	−	−	6	+	+	+	−	−	35–35	+	+	?
Jones *et al.* (12) (1995)	−	+	6	−	+	+	+	−	33–39	+	−	+
D'Souza *et al.*(17) (1996)	−	+	6	−	−	−	−	−	26	?	+	−
Lahdensuo *et al.* (16) (1996)	−	+	12	+	+	+	−	−	56–59	+	+	+

*When a control group is used, the numbers of patients in the intervention group and control group, respectively, are presented.
+, fulfils the specified criteria; −, does not fulfil the specified criteria; ±, does fulfil the specified criteria to some extent; ?, it is not clear from the published paper whether the specified criteria are fulfilled.

TABLE 2. Overview of contents of the self-treatment guidelines

Study	Type of guidelines*	PEF zones†	Action
Beasley *et al.* (3) (1989)	PEF	100–70	Continue regular medication
		70–50	Double inhaled steroids
		<50	Start oral steroids
		<150–200	Seek help
Worth (9)‡ (1990)	PEF and symptoms	Not mentioned	?
Mayo *et al.* (4) (1990)	PEF and symptoms	Not mentioned	?
Ringsberg *et al.* (6) (1990)	?	?	?
Charlton *et al.* (7,15) (1990 and 1991)	PEF or symptoms	100–70	Continue regular medication
		70–50	Double inhaled steroids
		50–30	Start oral steroids
		<30	Seek help
Mühlhauser *et al.* (5) (1991)	PEF and symptoms	Not mentioned	?
Charlton *et al.* (14) (1992)	PEF and symptoms	100–70	Continue regular medication
		70–50	Double inhaled steroids
		50–30	Start oral steroids
		<30	Seek help
Yoon *et al.* (8) (1993)§	PEF and symptoms	100–80	Continue regular medication
		80–70	Double inhaled steroids
		70–60	Start oral steroids
		<60	Seek help
GRASSIC (18) (1994)	PEF	Not mentioned (three unspecified levels)	Continue regular medication
			Start oral steroids
			Seek help
D'Souza *et al.*(10) (1994)	PEF and symptoms	100–80	Continue regular medication
		80–60	Double inhaled steroids
		60–40	Start oral steroids and call doctor
		<40	Seek help
Boulet *et al.* (13) (1995)	PEF	?	?
Ignacio-Garcia *et al.* (11) (1995)	PEF	100–70	Continue regular medication
		70–50	double inhaled steroids
		<50	Start oral steroids and seek help
Jones *et al.* (12) (1995)	PEF	100–75	Continue regular medication
		75–50	Double inhaled steroids
		50–25	Start oral steroids and call doctor
		<25	Seek medical help
D'Souza *et al.*(17) (1996)	PEF and symptoms	100–80	Continue regular medication
		80–60	Double inhaled steroids
		60–40	Start oral steroids and call doctor
		<40	Seek help
Lahdensuo *et al.* (16) (1996)	PEF	100–85	Continue regular medication
		85–70	Double inhaled steroids
		<70	Start oral steroids and seek help

*Guidelines based on PEF, symptoms, or both.
†Percentage of personal best PEF or percentage predicted.
‡Based on description from the same asthma education programme by Mühlhauser *et al.* (5).
§Based on reference to manuscript by Woolcock *et al.* (21).

Ignacio-Garcia *et al.* (Spain, 1995) (11) were able to show remarkable improvements in lung function and reductions in the number of exacerbations, days lost from work, physician consultations, emergency room admissions and number of hospital admissions, with a relatively small number of patients receiving individual counselling, compared with a control group that did not receive any education.

Jones and colleagues (UK, 1995) (12) have performed the only other randomized placebo-controlled trial among 72

patients to assess the efficacy of self-treatment based on home peak flow monitoring. There were no differences between the two groups in lung function, symptoms, quality of life and costs for treatment. Only the self-treatment group showed improvements in quality of life and disturbance of daily activities.

In another study, D'Souza *et al.* (New Zealand, 1996) (17) offered a 'credit-card' self-management plan to a group of 30 asthma patients discharged from the emergency department. The number of emergency department visits decreased significantly as well as asthma morbidity. Unfortunately, severe selection occurred in the recruitment of patients.

Lahdensuo and coworkers (Finland, 1996) (16) compared the efficacy of self-management of asthma with traditional treatment in 115 patients with mild to moderately severe asthma. The number of unscheduled visits to ambulatory care facilities, days off work and courses of antibiotics and prednisolone per patient were lower and the quality of life score was higher in the self-management group than in the traditionally treated group following the educational programme. No changes in lung function were observed.

In summary, the available evidence for the efficacy of guidelines for self-treatment is far from complete. Several studies show improvements in health outcomes, such as lung function, quality of life, use of health care facilities and asthma symptoms, but because of the lack of proper control groups, it is not clear whether this can be attributed to self-treatment or to other aspects of asthma self-management, such as more medical attention and education. The only two placebo-controlled studies showed only little or no effect of self-treatment guidelines. It has to be said, however, that those two studies did not provide patients with additional education or training.

The Paradigm of the Randomized Controlled Trial

Most studies mentioned above did not follow the principles of the RCT and its requirements, which is imperative for studies on drug efficacy. It should be noted that self-management research is relatively new to medicine, and clear guidelines on how to perform these studies, evaluating behavioural changes, were not available. The early studies evaluated the overall impact of self-management on morbidity or quality of life. Now it is time to identify the key elements (e.g. self-treatment) of a self-management programme. Given the present state of knowledge regarding self-management and self-treatment, there is no compelling reason why a self-management trial should not be executed as a placebo-controlled RCT, as the concept of testing the efficacy of self-treatment in asthma self-management training is identical to testing a new medical drug. A proper RCT on asthma self-management, trying to establish the added value of self-treatment guidelines, has to conform with at least three criteria: (1) relevance, (2) validity and (3) sufficient power and maximum efficiency (21).

RELEVANCE

(a) The trial should show relevance with regard to the intervention itself. The intervention to be tested should have the most potential to improve outcomes. In this respect, adding self-treatment guidelines to self-management education is intuitively logical.

(b) The trial should show relevance with regard to the intended health objectives. For self-management education, behavioural change is the minimum intended effect and should therefore be assessed.

(c) The trial should show relevance with regard to the intended patient population, so the study population has to reflect the population of asthmatics one is aiming to reach with the self-management programme.

VALIDITY

A trial should provide a valid i.e. unbiased, test of the efficacy of self-treatment guidelines. This means comparability of the following.

(a) *Populations.* Intervention- and control groups should have comparable distributions of patient characteristics and extraneous determinants that are predictive for the outcome of interest. This can be achieved by stratified randomization.

(b) *Effects.* Intervention and control strategies should give similar outcome results in case self-treatment guidelines are ineffective. To this end placebo treatment is necessary. For studies on the added value of self-treatment guidelines to self-management education, this can be achieved by giving an equal amount of (medical) attention and education to patients in the intervention group and the control group. The only difference between the groups should be the guidelines for self-treatment.

(c) *Information.* Double blinding (patients and observers) is introduced to prevent incomparability of information. As blinding is not easily achieved in asthma self-management research, objectivity and standardization of outcome measurements are crucial.

SUFFICIENT POWER AND MAXIMUM EFFICIENCY

(a) The number of patients has to be sufficient. This means that studies should have enough power to detect a relevant difference between groups of specified size.

(b) Homogeneous patient groups should be selected. Conditional on the number of patients, the power and efficiency of the study can be increased by selecting homogeneous patient groups.

(c) Patients should have a potential for improvement. However, the patients' asthma should be stable at the start of the study, for two reasons. First, self-treatment guidelines are based on a personal best PEF, but unstable patients will not reach their true maximal PEF. Secondly, if the patients asthma is not stable, improvements will probably occur because of more effective treatment.

Discussion of the Studies

Several points, important to the relevance of the outcomes, arise when evaluating the above-mentioned studies. Table 1 summarizes all 15 studies and the quality criteria mentioned above with regard to relevance, validity and sufficient power and maximum efficiency.

RELEVANCE

None of the interventions was explicitly based on behavioural principles and only six trials evaluated changes in behaviour following the programme using either questionnaires or peak flow diaries and/or medication reports. Yoon et al (8) used a questionnaire to obtain information on changes in self-management behaviour and found that the intervention group showed a greater proportional improvement (+66%) compared with the control group (−9%) on questions related to self-management skills. The GRASSIC study (18) evaluated self-efficacy in both groups but does not report on changes over time. Boulet and co-workers (13) included questions pertaining to 'what to do during exacerbations' in a knowledge questionnaire and they found a 21% increase in knowledge in the intervention group, 1 yr after the programme. Unfortunately it is not clear what the increase for the specific questions on behaviour during exacerbations was. Jones and colleagues (12) evaluated self-treatment behaviour during exacerbations of asthma using peak flow diaries. Of the 20 subjects (51%) who experienced an exacerbation nine (45%) were fully compliant with doubling inhaled steroids and a further three complied during at least half of their episodes (67% 'compliers' in total); eight (40%) never complied. It must be noted that compliance was based on self-report. In a study by D'Souza *et al.* (17) 20 of the 26 study participants (77%) stated that they had used the self-treatment instructions on the credit card to increase the amount of inhaled steroids. Of the ten patients who required a course of prednisone, six had self-initiated the treatment and four had initiated treatment with the assistance of a doctor. Both sides of the card (peak flow and symptoms) were found to be equally helpful by 50%, and 42% thought the peak flow side was more helpful. Lahdensuo and co-workers (16) used peak flow diary cards and noted that 32 patients (57%) had peak flow values falling more than 15% at least once during the study year, yielding a total of 141 episodes. Three patients (9%) did not double their inhaled steroids in any episode, 11 (34%) doubled the dose occasionally and 18 patients (56%) always doubled the dose. Peak flow values decreased more than 30% on 13 occasions and a course of oral prednisolone was started in ten instances.

Eight studies had a 1 yr follow-up period, while this varied from 4 to 10 months in the others. In general, a follow-up period should be long enough for desired changes to take place. On the other hand, patients might change their behaviour, immediately following the intervention, but the initial effect might wear off after a few months. Intuitively, and not supported by hard evidence, one would choose a period of 1 yr or preferably 2 yr of follow-up. One of the reasons is the influence of seasonal variation on lung function.

Selective sampling or participation occurred in at least seven studies. In two studies (7,14,15) the study population was recruited by invitational letters to eligible patients, leading to low response rates. Similarly, Jones (12) invited 90 GP practices to participate in their study, but only 25 successfully recruited patients. D'Souza (10) recruited Maori patients through 'established community networks, not resulting in a random selection of asthmatic individuals', and in another study only 13% of approached patients were included in the study (17). Yoon (8) personally identified 185 eligible and willing patients during their stay in hospital, of whom only 76 attended the single educational session. Attenders were predominantly female non-smokers with more than 10 yr of schooling. In the GRASSIC study a number of more severe patients were already prescribed a PEF meter before the start of the study and were therefore not eligible for randomization.

Finally, only six trials explicitly selected patients on inhaled or oral steroids prior to the study. This is an important factor, because it is very likely that patients who are not on inhaled or oral steroids prior to enrolment in the study will benefit from these medicines when they are added to their treatment regimen. Also, an increase in the dosage of inhaled or oral steroids would probably be beneficial to patients who are on a lower dose at the start of the study. In such instances, it would be incorrect to ascribe improved outcomes solely to the guidelines for self-treatment. In the study by Beasley *et al.* (3) eight patients (27%), previously not taking inhaled steroids, were on a maintenance dose of beclomethasone of 350 μg (200–1000 μg) at the final visit. In the 22 patients (73%) who were already on an average dose of 805 μg (200–2000 μg) at the initial visit, this increased to 1130 μg (200–2000 μg). Worth (9) trained patients who were admitted to hospital; during this 5-day course drug therapy was optimized. Information on medication use prior to admission is lacking. Mayo and colleagues (4) enrolled 56 patients in a self-management programme. Before enrolment, 20% were on chronic inhaled corticosteroids and 25% were on chronic daily prednisone. After enrollment this changed to 82% and 9% respectively. Ringsberg *et al.* included 38 patients in a 1 yr RCT, but 12 patients (32%) were not using steroids (6). No other information on medication use is presented, so it is not clear whether this had changed or not. Mühlhauser and coworkers (5) give a detailed description of the changes in medication in their patients. On admission 59 patients used on average 750 μg (400–1000 μg) of beclomethasone. At discharge this had increased to 65 patients using on average 920 μg (750–1000 μg). After 1 yr 70 patients were using on average 930 μg (750–1000 μg). For oral prednisolone the corresponding numbers were 57 patients using 14 mg day^{-1} (8–20 mg day^{-1}), 65 patients using 27 mg day^{-1} (15–40 mg day^{-1}) and 43 patients using 15 mg day^{-1} (8–20 mg day^{-1}). It is not clear from the data whether some patients were using both types of steroids or none. Yoon *et al.* (8) observed an increase in the use of inhaled steroids, from 43% of all patients, before admission, to 50%

in the intervention group and 61% in the control group after 10 months. The GRASSIC study did not state the number of patients on inhaled steroids, but as the dose of inhaled steroids did not change over the year, this will not have influenced results. In one study by D'Souza *et al.* (10) the percentage of patients reporting that they were prescribed inhaled steroids increased from 61% to 93%. The authors state 'Of perhaps greater health significance, is the increase from 39% to 91% of participants who indicated that inhaled steroids were prescribed for regular use.' In another study (17), the same research group found an increase in the use of inhaled steroids from 73% to 100% among the 26 patients who completed the study. The mean prescribed dose of inhaled steroids increased approximately two-fold.

VALIDITY

Seven trials used a pre-test post-test design. One trial (13) assigned patients to an intervention group and later matched these with a control group, while in six studies patients were randomized into an intervention or control group. When no control group is used, it is not possible to separate effects of the various components of the self-management programmme. Therefore, a pre-test post-test design is not suitable to test the efficacy of adding self-treatment to a self-management education programme. This is also true for controlled studies, when there are more differences between the intervention and control group than just the guidelines for self-treatment of exacerbations of asthma. If the control group is a 'regular care' control group, there will almost always be other differences in favour of the intervention group, such as more education and more time spent on them, more medical attention and often also alterations in the prescribed medication. Most of the controlled studies are not appropriately controlled with regard to self-treatment guidelines. For example, patients in the intervention group in Ignacio-Garcia *et al*s study (11) improved quite a lot compared with regular controls, but this does not necessarily mean that this is caused by the self-treatment guidelines. The favourable outcome measures could also be explained by patient education or more effective pharmacotherapeutic treatment. Probably many aspects, including self-treatment, contributed to the observed improvements, but to what extent cannot be determined. Therefore, with respect to the effect of the entire intervention as a whole, the study is adequately controlled, but, with regard to the single component of self-treatment guidelines, the study has to be considered inappropriately controlled. To overcome this problem, it is necessary to use a placebo-control group that will receive the same amount of education, time spent on them and medical attention and will also receive the same alterations in the prescribed medication as the intervention group. Only Jones and colleagues and the GRASSIC study designed a 'placebo' controlled study (12) and they were unable to demonstrate between-groups differences in lung function, symptoms, quality of life and costs for treatment. These two studies found no proof for the efficacy of self-treatment guidelines, but it must be noted that no formal education and/or training was provided; thus one cannot speak of the 'added value' of self-treatment to a self-management programme.

None of the studies used a single- or double-blind design, which is indeed difficult to achieve, especially if the physician is one of the researchers.

SUFFICIENT POWER AND MAXIMUM EFFICIENCY

Every published trial reported a treatment effect in at least one parameter. It is likely that negative studies, because of insufficient power, are selectively not reported (publication bias).

Explicit inclusion and exclusion criteria are seldom presented; this makes it difficult to judge the homogeneity of the study samples. Most studies selected patients whose lung function parameters could improve substantially, except in the study by Jones *et al.* (12), whose patients were all given oral steroids at the start of the study to optimize lung function.

In only seven studies could it be assumed that patients were stable at the start of the study. If patients are not well controlled at the first visit, it is very likely, that improvements in outcomes are, in part, caused by adequate medical treatment, following enrolment in the study.

In summary: of all studies described above, only two were placebo controlled and these studies failed to show evidence of the efficacy of self-treatment. The design of the other studies does not permit conclusions about the efficacy of self-treatment.

Suggestions for Future Research

It still is not clear whether guidelines for self-treatment are effective in reducing morbidity. To assess the added benefit of self-treatment guidelines to a self-management programme, randomized, 'placebo' controlled trials of sufficient size with sufficient follow-up time are necessary. These studies should be done in patients in general practice, hospital outpatients and hospitalized patients. The only difference between intervention and control groups should be guidelines for self-treatment. At least one self-management trial incorporating self-treatment guidelines, in an adult outpatients asthma population, is underway in The Netherlands, following the paradigm of the RCT. So far, study results seem promising as to the role of self-management and self-treatment in the improvement of asthma care. Results of additional studies with proper design, addressing the efficacy of self-treatment guidelines, should be available before these time-consuming and expensive programmes are offered to adult asthmatics.

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